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ORDER INFORMATION

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450 mg Tablet Tablet Bottle (20 tablets) NDC# 70842-0101-01	300 mg Vial Single-Dose Vial (Tray of 10 Vials) NDC# 70842-0102-03
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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS, and EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue BAXDELA immediately and avoid the use of fluoroquinolones, including BAXDELA, in patients who experience any of these serious adverse reactions.

Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid BAXDELA in patients with known history of myasthenia gravis.

Contraindications

BAXDELA is contraindicated in patients with known hypersensitivity to delafloxacin or any of the fluoroquinolone class of antibacterial drugs, or any of the components of BAXDELA.

Warnings and Precautions

If any of the following reactions occur in patients receiving BAXDELA, discontinue treatment immediately and institute appropriate clinical measures. Avoid using BAXDELA in patients with a known history of any of these conditions. These reactions may occur after the first dose or with subsequent doses.

Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy and Central Nervous System Effects:

- Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions from different body system.
- Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion).



IMPORTANT SAFETY INFORMATION (cont'd)

Tendinitis and Tendon Rupture:

- Fluoroquinolones have been associated with an increased risk of tendinitis and tendon rupture in all ages. Tendinitis or tendon rupture can occur, within hours or days of starting a fluoroquinolone, or as long as several months after completion of fluoroquinolone therapy. Tendinitis and tendon rupture can occur bilaterally.
- This risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients over age 60 years of age, in patients taking corticosteroid drugs, and, in patients with kidney, heart, and lung transplant. Other factors that may independently increase the risk of tendon rupture include strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis.
- Discontinue BAXDELA immediately if the patient experiences pain, swelling, inflammation or rupture of a tendon.

Peripheral Neuropathy:

- Fluoroquinolones have been associated with an increased risk of peripheral neuropathy. Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias, and weakness have been reported in patients receiving fluoroquinolones, including BAXDELA. Symptoms may be irreversible in some patients.
- Discontinue BAXDELA immediately if the patient experiences symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation and/or motor strength in order to minimize the development of an irreversible condition.

Central Nervous System Effects:

- Psychiatric Adverse Reactions:** Fluoroquinolones, including BAXDELA, have been associated with an increased risk of psychiatric adverse reactions.
- Central Nervous System Adverse Reactions:** Fluoroquinolones have been associated with an increased risk of seizures, increased intracranial pressure, dizziness, and tremors.

Exacerbation of Myasthenia Gravis:

- Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Post-marketing serious adverse reactions, including death and requirement for ventilator support, have been associated with fluoroquinolone use in persons with myasthenia gravis.

Hypersensitivity Reactions:

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving fluoroquinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial edema, dyspnea, urticaria, and itching. Hypersensitivity reactions have been reported in patients receiving BAXDELA.

Clostridium difficile-Associated Diarrhea:

- Clostridium difficile*-associated diarrhea (CDAD) has been reported in users of nearly all systemic antibacterial drugs, including BAXDELA, with severity ranging from mild diarrhea to fatal colitis.
- C. difficile* produces toxins A and B, which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antibacterial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use.
- If CDAD is suspected or confirmed, ongoing antibacterial use not directed against *C. difficile* should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Risk of Aortic Aneurysm and Dissection:

- Epidemiologic studies report an increased risk of aortic aneurysm and dissection within two months following use of fluoroquinolones, particularly in elderly patients. In patients with a known aortic aneurysm or patients who are at greater risk for aortic aneurysms, reserve BAXDELA for use only when there are no alternative antibacterial treatments available.

Development of Drug-Resistant Bacteria:

- Prescribing BAXDELA in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Blood Glucose Disturbances:

- Fluoroquinolones have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glyburide) or with insulin. In these patients, careful monitoring of blood glucose is recommended. Severe cases of hypoglycemia resulting in coma or death have been reported with other fluoroquinolones.

Adverse Reactions

The most common adverse reactions ($\geq 2\%$) in patients treated with BAXDELA were nausea, diarrhea, headache, transaminase elevations, and vomiting.

INDICATIONS AND USAGE:

Acute Bacterial Skin and Skin Structure Infections (ABSSSI): BAXDELA is indicated in adults for the treatment of acute bacterial skin and skin structure infections.

Community-Acquired Bacterial Pneumonia (CABP): BAXDELA is indicated in adults for the treatment of community-acquired bacterial pneumonia.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BAXDELA and other antibacterial drugs, BAXDELA should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

Please see [full Prescribing Information](#), including [Boxed Warning](#), and the [Patient Medication Guide](#).


Baxdela[®]
(delafloxacin) 450 mg tablets
300 mg vial for injection



Product Information:

- 1-844-633-6568
- www.baxdela.com

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